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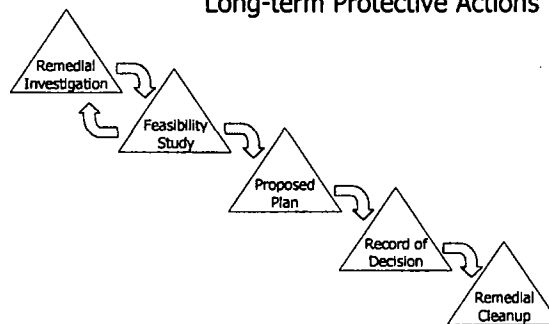
Superfund Division Directors Meeting

Managing a Cleanup
in the Face of Public Health Effects
and Uncertain Endpoints

The Libby, Montana Superfund Site

Baltimore, Maryland
May 28, 2008

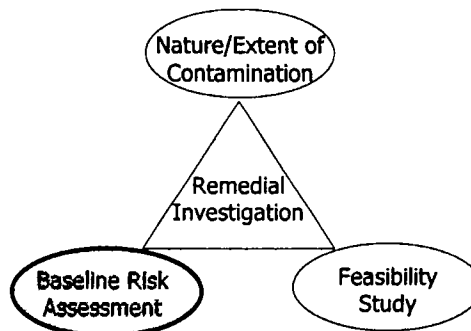
The Superfund Remedial Process Long-term Protective Actions



Superfund Remedial Process

- Traditional Approach
 - Baseline Risk Assessment helps guide cleanup decision
- Deciding on a Cleanup Option (Nine Evaluation Criteria)
 - Overall protection of human health and environment
 - Compliance with applicable or relevant and appropriate requirements
 - Long term effectiveness and permanence
 - Reduction of toxicity, mobility, or volume
 - Short-term effectiveness
 - Implementability
 - Cost
 - State acceptance
 - Community acceptance

The Baseline Risk Assessment is Part of the Remedial Investigation



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But how do you manage a cleanup when...

- Significant exposures are occurring among the population;
- Clear evidence of attributable, measurable disease in exposed population is present;
- Available toxicity data are highly uncertain, inapplicable, or absent?

Consider the first evaluation criteria:

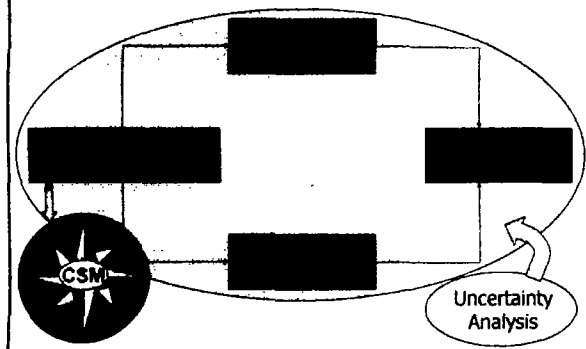
"Overall protection of human health and the environment."

Initial Phase

Cleanups are driven by exposures

- Importance of Conceptual Site Model (CSM)
- Consider multiple pathways of exposure
- Consider multiple routes of exposure
 - Inhalation, ingestion, etc.
- Don't ignore cumulative exposure
- Identify site-specific exposure parameters
 - Exposure frequency, exposure duration, etc.

Baseline Risk Assessment *Conceptual Site Model (CSM)*



Conceptual Site Model (CSM)

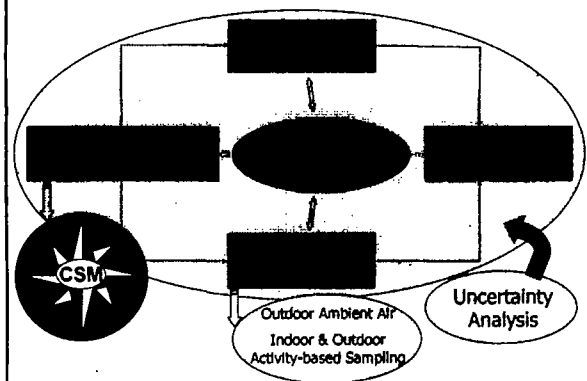
- Identifies origin of contamination
- Illustrates movement through the environment
- Identifies receptors & routes of exposure
- Describes potential exposure pathways
- Helps guide development of the *Baseline Risk Assessment*

Refer to handout of CSM
for Libby OU4 here if desired.

Step 1: Reduce Exposures

- Use CSM to help rank exposures
 - Source material
 - Significant exposure pathways
- Tackle worst first
- Goal is to eliminate or reduce significant exposure pathways
- Collect representative data for suspected significant exposure pathways lacking data
 - In Libby, these were/are
 - Outdoor ambient air monitoring
 - Indoor/outdoor activity-based sampling
 - Evaluation of tradesperson exposures

Baseline Risk Assessment



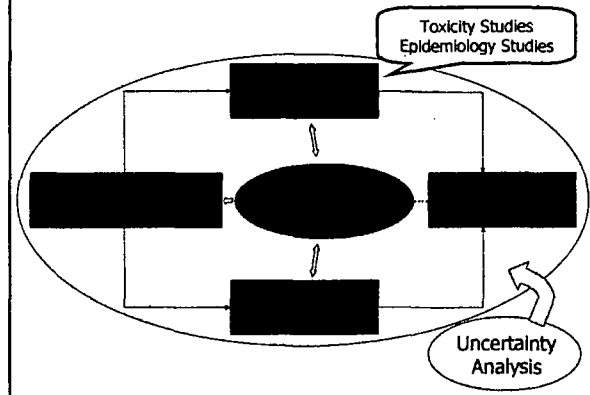
Step 2: Address Public Health Effects

- Clear evidence of attributable, measurable disease in exposed population is present
- Work with other public health agencies to obtain support for affected population
 - Agency for Toxic Substances and Disease Registry

Step 3: Address Shortcomings of Toxicity Data

- Typical approach to remediation
 - Are exposures above or below levels of concern based on known toxicity?
- What if available toxicity data are highly uncertain, inapplicable, and/or absent?
- How to determine what that level of concern is when current toxicity values are of limited applicability?

Baseline Risk Assessment



money

Toxicity Assessment

- Epidemiological studies
 - Consider high level & low level exposures in population
 - Biomarkers of exposure
 - Evaluate efficacy of cleanups
- Focused toxicity studies
 - Design for most powerful predictive capabilities
 - Screening evaluations
 - In vitro studies
 - In vivo studies
 - Mode of action paradigm
 - Internal dosimetry

Using Existing but Nonspecific Toxicity Information

- Advantages
 - Allows interim or screening level evaluation of risks to help guide cleanup approach
 - Enables progress in cleanup prioritization
 - Based on best available science
- Disadvantages
 - May set precedent for future or other national cleanups
 - May over- or underestimate risks
- Public acceptance may or may not be an issue

Toxicity Data Uncertainties

- Chemical specific uncertainties
 - For example, for Libby Amphibole, mineralogy
 - If dealing with asbestos, must also consider morphology
- Uncertainties in derivation of existing values
 - Historical methodological limitations (e. g., sampling/analysis)
 - Exposure reconstruction
 - Disease classification
- Alternate models for evaluation of risk

References

- Include reference to TRW framework